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EXAMINER
SEREBOFF, NEAL

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

		Application No.	Applicant(s)
Office Action Summary		10/089,708	ANDERSON ET AL.
		Examiner	**Art Unit**	
		Neal R. Sereboff	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _12 June 2002_.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-77_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-77_ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All b) ☐ Some * c) ☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _4/1/2002_.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1.   Claims 1 - 77 are pending and the Information Disclosure Statement (PTO-1449)

submitted on 4/1/2002 has been considered.

2.   (MPEP 2106.01) Descriptive material can be characterized as either "functional

descriptive material" or "nonfunctional descriptive material." "Nonfunctional descriptive

material" includes but is not limited to music, literary works, and a compilation or mere

arrangement of data.

When nonfunctional descriptive material is recorded on some computer-readable medium, in a

computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under

35 U.S.C. **101**. In addition, USPTO personnel should inquire whether there should be a rejection

under 35 U.S.C. **102** or **103**. USPTO personnel should determine whether the claimed

nonfunctional descriptive material be given patentable weight. USPTO personnel must consider

all claim limitations when determining patentability of an invention over the prior art. *In re*

Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may

not disregard claim limitations comprised of printed matter. See *Gulack*, 703 F.2d at 1384, 217

USPQ at 403; see also *Diehr*, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel

need not give patentable weight to printed matter absent a new and unobvious functional

relationship between the printed matter and the substrate. See *In re Lowry*, 32 F.3d 1579, 1583-

84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed.

Cir. 2004).

Claim Objections

3.   Claim 72 is objected to because of the following informalities: Claim 72 is toward "a

network computer system" of claim 1 while claim 1 includes "a network computer system." The

examiner understands 72 to be dependent upon claim 1 and therefore "a network computer

system" should be "the network computer system." Appropriate correction is required.

Claim Rejections - 35 USC § 102

4.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed
> in the United States before the invention by the applicant for patent or (2) a patent granted on an application for
> patent by another filed in the United States before the invention by the applicant for patent, except that an
> international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this
> subsection of an application filed in the United States only if the international application designated the United
> States and was published under Article 21(2) of such treaty in the English language.

5.   **Claims 1 – 8, 14 – 19, 22 – 28, 32 – 44, 46 – 50, 60 – 68 and 72 – 77** are rejected under

35 U.S.C. 102(e) as being anticipated by Martino, U.S. Patent Number 6,044,382.

6.   As per claim 1, Martino teaches a system for collecting and providing selective access to

medical data relevant to plural patients having related medical conditions comprising a network

computer system;

- Associated with the network computer system, a first patient-specific database (see

    column 26, lines 42 – 65) and a second condition-specific database (see column 29, lines

    27 – 54 where the second database determines the actions performed next if a change is

    detected);

- Remote from said network computer system, plural patient electronic data collectors, each for collecting patient data relevant to a particular patient's medical condition (see column 28, lines 42 – 51 where a monitor is set up remotely);

- Associated with each patient electronic data collector, a communicator for communicating with an entrypoint to said network computer system to enable transfer of said patient data to said first patient-specific database and to said second condition-specific database (see column 28, lines 42 – 51 where the connection is performed using a modem);

- A first secure access gateway permitting access to the first patient-specific database in response to a first user authorisation command (see column 24, lines 55 – 67 where authorization limits access); and

- A second secure access gateway permitting access to the second condition-specific database in response to a second user authorisation command (see column 24, lines 55 – 67 where authorization limits access).

7.   As per claim 2, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein said patient electronic data collector collects said patient data on a regular basis (see column 29, line 55 through column 30, line 9).

8.   As per claim 3, Martino teaches the system of claim 2 as described above. Martino further teaches the system wherein said patient electronic data collector collects said patient data on a continuous basis (see column 29, line 55 through column 30, line 9).

9.   As per claim 4, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein said patient data comprises diagnostic data for use in

diagnosing each patient's medical condition (see column 29, lines 27 – 54 where vital signs are collected).

10.   As per claim 5, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein said patient data comprises compliance data for use in assessing each patient's compliance with a treatment or prescribing regime (see column 29, line 55 through column 30, line 9 where the patient is reminded to perform a function and his vital signs are then monitored and thus determining compliance).

11.   As per claim 6, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein each patient has a similar or identical medical condition (see column 30, lines 4 – 9 where the patients have similarly critical medical conditions).

12.   As per claim 7, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein each patient is on a similar or identical treatment or prescribing regime (see column 28, line 52 through column 29 line 25 where the patient uses the same forms and therefore the same treatments depending upon the forms answers).

13.   As per claim 8, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein each patient electronic data collector is under the control of an individual patient (see column 28, line 52 through column 29 line 25 where the patient has the monitors at his house).

14.   As per claim 14, Martino teaches the system of claim 1 as described above. Martino further teaches the system wherein the communicator is capable of communicating wirelessly with the entrypoint to the network computer system (see column 3, line 66 through column 4, line 21).

15.   As per claim 15, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the patient data is communicable between the patient

electronic data collector and the network computer system in encrypted form (see column 24,

line 55 – 67).

16.   As per claim 16, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the patient data is continuously communicable between the

patient electronic data collector and the network computer system (see column 29, line 55

through column 30, line 9).

17.   As per claim 17, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the patient data is communicable in packet form between the

patient electronic data collector and the network computer system (see column 10, lines 52 – 67).

18.   As per claim 18, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the network computer system is under the control of a

healthcare data manager (see column 28, lines 42 – 51 where the doctor controls the system).

19.   As per claim 19, Martino teaches the system of claim 18 as described above. Martino

further teaches the system wherein the healthcare data manager is associated with a healthcare

organisation selected from the group consisting of a doctor's practice, a hospital, a healthcare

management centre and a pharmaceutical company (see column 28, lines 42 – 51 where the

organization is a doctor's practice).

20.   As per claim 22, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the data within either database is partitioned according to

level of confidentiality or level of commercial sensitivity (see column 24, line 54 through

column 25, line 4 where the different security levels allow for different levels of database

access).

21.   As per claim 23, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the first and second secure access gateways are distinct from

each other (see column 29, lines 55 – 67 where the access is at a patient's home or at a medical

kiosk).

22.   As per claim 24, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the first and second secure access gateways are coupled or

arranged in series (see column 32, lines 1 – 16 where the gateways are coupled through the

Internet).

23.   As per claim 25, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the secure access gateways are password protected (see

column 28, lines 52 – 67).

24.   As per claim 26, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the first and second user authorisation commands are distinct

(see column 28, lines 52 – 67 where the nurse and the patient have different security levels and

the nurse can access more information).

25.   As per claim 27, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the first and second user authorisation commands are

identical (see column 28, lines 52 – 67 where the nurse can access more information than the

patient and thus access both patient information and diagnosis information).

26.   As per claim 28, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the authorised users are selected from the group consisting of

the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research

professional, a database manager and any combinations thereof (see column 28, lines 52 – 67

where the nurse is a healthcare professional).

27.   As per claim 32, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein information from a remote datasource is made available to the

network computer system (see figure 11 where all databases are connected through the Internet).

28.   As per claim 33, Martino teaches the system of claim 32 as described above. Martino

further teaches the system wherein said remote datasource comprises data relating to ambient

environmental conditions (see column 26, lines 42 – 65 where the ambient conditions are

recorded by video and further where the exact information stored within a database is

nonfunctional).

29.   As per claim 34, Martino teaches the system of claim 32 as described above. Martino

further teaches the system wherein the remote datasource comprises a database of prescribable

medicaments (see column 19, lines 22 – 40 where the database includes prescription information

and further where the exact information stored within a database is nonfunctional).

30.   As per claim 35, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the patient electronic data collector further comprises

- A patient electronic data management system comprising a memory for storage of data
  (see column 7, lines 41 – 67 where the computer has memory as shown in column 7, lines
  16 – 40);

- A microprocessor for performing operations on said data (see column 7, lines 41 – 67); and

- A transmitter for transmitting a signal relating to the data or the outcome of an operation on the data (see column 8, lines 29 – 60 where the information is sent to a display).

31.   As per claim 37, Martino teaches the system of claim 35 as described above. Martino further teaches the system wherein the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system (see column 5, lines 39 – 60 where the network is two-way).

32.   As per claim 38, Martino teaches the system of claim 1 as described above. Martino further teaches the system additionally comprising

- An authorised user data communicator comprising

  o An authorised user electronic data management system comprising

    - A memory for storage of data (see column 7, lines 41 – 67 where the computer has memory as shown in column 7, lines 16 – 40);

    - A microprocessor for performing operations on said data (see column 7, lines 41 – 67); and

    - A transmitter for transmitting a signal relating to the data or the outcome of an operation on the data (see column 8, lines 29 – 60 where the information is sent to a display); and

  o A communicator for communicating with an entrypoint to a network computer system to enable communication of data between the network computer system

and the authorised user electronic data management system (see column 8, lines

29 – 60 where the information is sent to a display).

33.   As per claim 39, Martino teaches the system of claim 38 as described above. Martino

further teaches the system for the remote assessment of a patient's medical condition and remote

prescription therefor comprising

- A first authorised user data communicator capable of communicating a prescription

   authorisation command to the network computer system (see column 26, lines 42 – 65

   where the data transaction system transmits a prescription to a pharmacist); and

- A second authorised user data communicator capable of receiving a prescription

   authorisation command from the network computer system (see column 26, lines 42 – 65

   where the pharmacist receives the transmitted prescription).

34.   As per claim 40, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein any communicator employs radiofrequency or optical signals

(see column 38, lines 25 – 29).

35.   As per claim 41, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein any communicator communicates with the network computer

system via a gateway thereto (see column 5, lines 38 – 59 where the devices are networked).

36.   As per claim 42, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the communicator includes an embedded network server (see

column 4, line 66 through column 5, line 13 where the server is part of the network described in

column 5, lines 38 – 59).

37.   As per claim 43, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the communicator communicates with the network computer

system via a second communications device having telecommunications capability (see column

5, lines 38 – 59 where the network could be cellular).

38.   As per claim 44, Martino teaches the system of claim 43 as described above. Martino

further teaches the system wherein the telecommunications device comprises a cellular phone or

pager (see column 32, lines 1 – 16 where the device includes a cellular phone).

39.   As per claim 46, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the communicator communicates with a specifiable network

address of the network computer system (see column 5, lines 39 – 60 where 2 ore more devices

communicate with each other over a network).

40.   As per claim 47, Martino teaches the system of claim 46 as described above. Martino

further teaches the system wherein the specifiable network address is selected from the group

consisting of a web-site address, an e-mail address and a file transfer protocol address (see

column 7, lines 41 – 67 where a web-site address is used to download information).

41.   As per claim 48, Martino teaches the system of claim 35 as described above. Martino

further teaches the system wherein the patient electronic data management system additionally

comprises a data input system for patient input of data to the electronic data management system

(see column 8, lines 42 – 65 where patient data is inputted).

42.   As per claim 49, Martino teaches the system of claim 48 as described above. Martino

further teaches the system wherein said data input system comprises a man machine interface

selected from a keypad, graphical user interface (GUI), voice recognition interface or biometrics

interface (see column 8, lines 42 – 65 where the input system comprises a keyboard).

43.   As per claim 50, Martino teaches the system of claim 35 as described above. Martino

further teaches the system comprising a display for display of data from the patient electronic

data management system to the patient (see column 7, lines 41 – 67 where a display is used to

present the information).

44.   As per claim 60, Martino teaches the system of claim 1 as described above. Martino

further teaches the system wherein the plural patients have related cardiovascular conditions and

each patient electronic data collector additionally comprises a sensor which senses the

cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the

patient electronic data collector (see column 28, line 52 through column 29, line 25 where the

blood pressure monitor connects directly to the system and where the patient type is non-

functional descriptive information).

45.   As per claim 61, Martino teaches the system of claim 60 as described above. Martino

further teaches the system wherein said sensor measures the blood pressure of the patient (see

column 28, line 52 through column 29, line 25).

46.   As per claim 72, Martino teaches the system of claim 1 as described above. Martino

further teaches the (a) network computer system comprising

    • An interface capable of receiving patient data in electronic form from plural patient

        electronic data collectors (see column 28, line 52 through column 29, line 25 where the

        ports are the interface);

- Associated with said interface, a first patient-specific database (see column 26, lines 42 –

  65) and a second condition-specific database for storing said patient data database (see

  column 26, lines 42 – 65 where the patient data is stored within the same database); and

- An authorised user inquiry system comprising either or both of

  (a) A first secure access gateway permitting access to the first patient-specific database in

  response to a first user authorisation command;

  o First search means for searching said patient-specific database in response to a

  first authorised user inquiry (see column 19, line 1 – 20 where the web interface

  allows for searching the database); and

  o First results transmitting means for transmitting the results of said first authorised

  user inquiry to the first authorised user (see column 19, line 1 – 20 where the web

  interface allows for searching the database and where the results are then

  displayed within the browser);

  (b) A second secure access gateway permitting access to the second condition-specific

  database in response to a second user authorisation command;

  o Second search means for searching said second condition-specific database in

  response to a second authorised user inquiry; and

  o Second results transmitting means for transmitting the results of said second

  authorised user inquiry to the second authorised user, wherein the patient data

  originates remotely from the network computer system.

47.   As per claim **73**, Martino teaches the network computer system of claim 72 as described

above. Martino further teaches the network computer system wherein the network address

comprises a web-site address or a file transfer protocol address (see column 19, lines 1 – 20

where a web-site address is used).

48.   As per claim 62, Martino teaches a method for collecting and providing selective user

access to medical data relevant to plural patients having related medical conditions comprising

- Locally collecting patient data relevant to each patient's medical condition in electronic

  form (see column 28, lines 42 – 52 where the system is set up within a doctor's office);

- Communicating with an entry-point to a network computer system to enable transfer of

  said patient data to a first patient-specific database and to a second condition-specific

  database of said network computer system (see column 7, lines 41 – 67 where the entry-

  point and the databases are connected by the Internet which allows for data

  communication); and

- Permitting first authorised user access to the first patient-specific database via a first

  secure access gateway (see column 24, lines 55 – 67 where authorization limits access),

  and/or permitting second authorised user access to the second condition-specific database

  via a second secure access gateway.

49.   As per claim 63, Martino teaches the method of 62 as described above. Martino further

teaches the method comprising collecting the data on a regular basis (see column 29, line 55

through column 30, line 9).

50.   As per claim 64, Martino teaches the method of 62 as described above. Martino further

teaches the method comprising collecting the data on a continuous basis (see column 29, line 55

through column 30, line 9).

51.   As per claim 65, Martino teaches the method of 62 as described above. Martino further

teaches the method comprising communicating the data in encrypted form (see column 24, line

55 – 67).

52.   As per claim 66, Martino teaches the method of 62 as described above. Martino further

teaches the method wherein the data is continuously communicable (see column 29, line 55

through column 30, line 9).

53.   As per claim 67, Martino teaches the method of 62 as described above. Martino further

teaches the method wherein the data is communicable in packet form (see column 10, lines 52 –

67).

54.   As per claim 68, Martino teaches the method of 62 as described above. Martino further

teaches the method comprising permitting different levels of access to the data to different

authorised users (see column 24, line 54 through column 25, line 4 where the different security

levels allow for different levels of database access).

55.   As per claim 74, Martino teaches a method for collecting and providing selective user

access to medical data relevant to plural patients having related medical conditions, the method

comprising

- Receiving data relevant to each patient's medical condition collected automatically at a

    plurality of locations (see column 28, lines 42 – 51 where a monitor is set up remotely);

- Storing some or all of the received data in a first, patient-specific database (see column 5,

    lines 1 – 14 where the data stored within the relevant database);

- Storing some or all of the received data in a second, condition-specific database (see

    column 5, lines 1 – 14 where the data stored within the relevant database);

- Allowing access to said first database in response to a first user authorisation command (see column 24, lines 55 – 67 where authorization limits access); and

- Allowing access to said second database in response to a second user authorisation command (see column 24, lines 55 – 67 where authorization limits access).

56.   As per claim 75, Martino teaches the method of claim 74 as described above. Martino further teaches the method wherein the data is received and access to the databases is allowed via a network using TCP/IP (see column 7, lines 41 – 67 where the information is sent via the Internet and as shown in Reference U, the Internet is a global network of computer networks based on the TCP/IP protocol.).

57.   As per claim 76, Martino teaches the method of claim 74 as described above. Martino further teaches the method comprising program means for, when executed on a computer, instructing the computer to perform all of the steps (see column 17, lines 33 – 54).

58.   As per claim 77, Martino teaches a computer program product comprising

- A computer readable recording medium having recorded thereon a computer program comprising

  o Code means for, when executed on a computer, instructing said computer to perform the steps (see column 17, lines 33 – 54) of

    ▪ Receiving data relevant to each patient's medical condition collected automatically at a plurality of locations (see column 28, lines 42 – 51 where a monitor is set up remotely);

- Storing some or all of the received data in a first, patient-specific database (see column 5, lines 1 – 14 where the data stored within the relevant database);

- Storing some or all of the received data in a second, condition-specific database (see column 5, lines 1 – 14 where the data stored within the relevant database);

- Allowing access to said first database in response to a first user authorisation command (see column 24, lines 55 – 67 where authorization limits access); and

- Allowing access to said second database in response to a second user authorisation command (see column 24, lines 55 – 67 where authorization limits access).

Claim Rejections - 35 USC § 103

59.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

60.   **Claims 9 – 13 and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Abreu, U.S. Pre-Grant Publication Number 2002/ 0049389.

61.   As per claim 9, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach the system wherein any patient electronic data collector <u>is</u>

<u>integrated with a system for the delivery of medicament</u>.

However, Abreu teaches the system wherein any patient electronic data collector is integrated

with a system for the delivery of medicament (see paragraph 102).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art at would have added this feature into

Martino with the motivation to provide a novel drug delivery system for the treatment of eye and

systemic diseases (see Abreu paragraph 199).

62.   As per claim 10, Martino in view of Abreu teaches the system of claim 9 as described

above.

Martino does not explicitly teach a system wherein the <u>medicament delivery system provides</u>

<u>respirable delivery of medicament to the patient</u>.

However, Abreu teaches a system wherein the medicament delivery system provides respirable

delivery of medicament to the patient (see paragraph 1112).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art at would have added this feature into

Martino with the motivation to provide a novel drug delivery system for the treatment of eye and

systemic diseases (see Abreu paragraph 199).

63.   As per claim 11, Martino in view of Abreu teaches the system of claim 9 as described

above.

Martino does not explicitly teach a system wherein the <u>medicament delivery system provides</u>

<u>injectable delivery of medicament to the patient</u>.

However, Abreu teaches a system wherein the medicament delivery system provides injectable delivery of medicament to the patient (see paragraph 1112).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (see Abreu paragraph 199).

64.   As per claim 12, Martino in view of Abreu teaches the system of claim 9 as described above.

Martino does not explicitly teach a system wherein the medicament delivery system is an implant in the body of the patient.

However, Abreu teaches a system wherein the medicament delivery system is an implant in the body of the patient (see paragraph 1112 where the insulin pump is partially implanted).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (see Abreu paragraph 199).

65.   As per claim 13, Martino in view of Abreu teaches the system of claim 9 as described above.

Martino does not explicitly teach a system wherein the patient electronic data collector and the system for delivery of medicament are comprised within a handheld device (see paragraph 1019 where the device is a wristband).

However, Abreu teaches a system wherein the patient electronic data collector and the system for delivery of medicament are comprised within a handheld device.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (see Abreu paragraph 199).

66.   As per claim 36, Martino the system of claim 35 as described above.

Martino does not explicitly teach a system wherein said patient electronic data management system additionally comprises a geographic positioning system.

However, Abreu teaches a system wherein said patient electronic data management system additionally comprises a geographic positioning system (see paragraph 243).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art at would have added this feature into Martino with the motivation to provide a novel drug delivery system for the treatment of eye and systemic diseases (see Abreu paragraph 199).

67.   **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S. Patent Number 6,044,382 in view of Legal Precedent.

68.   As per claim 20, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach the system wherein the first patient-specific database and the second condition-specific database are separate from each other.

It is the Examiner's position that absent evidence of new or unexpected results, it is not inventive in terms of patentability to take one or more databases (D_1, D_2, D_3, . . . D_N) which store one or

more pieces of information (I_1, I_2, I_3, ... I_N) and add (or subtract) an additional number of

databases (X) to store all or part of the same information by allocating the data between the

various databases (that is, D_1 and D_{N+1} store I_1; D_2 and D_{N+2} store I_2; D_3 and D_{N+3} store I_3; ...

while D_N and D_{N+X} store I_N).

A modification increasing the number of databases (for example, having two databases store

information previously stored by just one database) is analogous to making functions, structures,

or actions separable. It is the Examiner's position that when the difference between the claimed

invention and the prior art is that the prior art does not disclose an element as separable, as a

matter of law, it would have been obvious to one having ordinary skill in the art to make the

element separable. *See* MPEP §2144.04 V. C. and *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ

348, 349 (CCPA 1961). It is desirable to allocate the database information to various databases

to enhance data management by organizing content, freeing up hard drive space, and speeding up

processing speeds because less data has to be searched.

Examiner posits that Applicants have not asserted any new or unexpected results

regarding their hardware configuration (and the software running their hardware configuration)

of their server system. Absent such new or unexpected results, such modifications either

increasing or decreasing the number of databases would have helped maintain benefits from

economies of scale in addition to offering excellent data management, fast response, and room

for expansion.

Therefore if the claimed database was not directly disclosed, it would have been obvious

to a person having ordinary skill in the art at the time the invention was made to modify Martino

to include the additional claimed database. Such a modification would have helped maintain

benefits from economies of scale in addition to offering excellent data management, fast

response, and room for expansion.

69.   As per claim 21, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach the system wherein the first patient-specific database is a sub-

database of the second condition-specific database.

It is the Examiner's position that absent evidence of new or unexpected results, it is not inventive

in terms of patentability to take one or more databases $(D_1, D_2, D_3, \ldots D_N)$ which store one or

more pieces of information $(I_1, I_2, I_3, \ldots I_N)$ and add (or subtract) an additional number of

databases (X) to store all or part of the same information by allocating the data between the

various databases (that is, D_1 and D_{N+1} store I_1; D_2 and D_{N+2} store I_2; D_3 and D_{N+3} store I_3; ...

while D_N and D_{N+X} store I_N).

A modification increasing the number of databases (for example, having two databases store

information previously stored by just one database) is analogous to making functions, structures,

or actions separable. It is the Examiner's position that when the difference between the claimed

invention and the prior art is that the prior art does not disclose an element as separable, as a

matter of law, it would have been obvious to one having ordinary skill in the art to make the

element separable. *See* MPEP §2144.04 V. *C.* and *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ

348, 349 (CCPA 1961). It is desirable to allocate the database information to various databases

to enhance data management by organizing content, freeing up hard drive space, and speeding up

processing speeds because less data has to be searched.

Examiner posits that Applicants have not asserted any new or unexpected results

regarding their hardware configuration (and the software running their hardware configuration)

of their server system. Absent such new or unexpected results, such modifications either

increasing or decreasing the number of databases would have helped maintain benefits from

economies of scale in addition to offering excellent data management, fast response, and room

for expansion.

Therefore if the claimed database was not directly disclosed, it would have been obvious to a

person having ordinary skill in the art at the time the invention was made to modify Martino to

include the additional claimed database. Such a modification would have helped maintain

benefits from economies of scale in addition to offering excellent data management, fast

response, and room for expansion.

70.   **Claims 29, 30 and 69 – 71** are rejected under 35 U.S.C. 103(a) as being unpatentable

over Martino, U.S. Patent Number 6,044,382 in view of Freeman et al, U.S. Patent Number

6,012,035.

71.   As per claim 29, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach a system wherein <u>access to either one or both of the databases</u>

<u>involves payment of a fee through an electronic payment means.</u>

However, Freeman teaches a system wherein access to either one or both of the databases

involves payment of a fee through an electronic payment means (see column 5, lines 30 – 41).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this

feature into Martino. One of ordinary skill in the art would have added this feature into Martin

with the motivation to provide the monitoring and management of a cooperative health care

provision system through a management service (see Freeman column 3, lines 35 – 37).

72.   As per claim 29, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach a system wherein <u>communication of patient data to either one</u> <u>or both of the databases results in award of an incentive payment through an electronic payment</u> <u>means.</u>

However, Freeman teaches a system wherein communication of patient data to either one or both of the databases results in award of an incentive payment through an electronic payment means (see Addendum, Processing and Electronic Payment of "Yes Credit" claims where the JustCare members receive an incentive discount).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martin with the motivation to provide the monitoring and management of a cooperative health care provision system through a management service (see Freeman column 3, lines 35 – 37).

73.   As per claim 69, Martino teaches the method of 62 as described above.

Martino further teaches the method comprising

- A first authorised user communicating a prescription authorisation command to the network computer system (see column 26, lines 42 – 65 where the data transaction system transmits a prescription to a pharmacist);

- A second authorised user receiving said prescription authorisation command from the network computer system (see column 26, lines 42 – 65 where the pharmacist receives the transmitted prescription).

Martino does not explicitly teach said second authorised user <u>preparing the prescription based on</u> <u>the prescription authorisation.</u>

However, Freeman teaches said second authorised user preparing the prescription based on the

prescription authorisation (see column 8, lines 37 – 43 where the prescription is filled).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this

feature into Martino. One of ordinary skill in the art would have added this feature into Martin

with the motivation to provide the monitoring and management of a cooperative health care

provision system through a management service (see Freeman column 3, lines 35 – 37).

74.   As per claim 71, Martino in vie of Freeman teaches the method of 69 as described above.

Martino further teaches the method wherein the first authorised user communicates the

prescription authorisation in response to a 'update prescription' alerting signal visible at a patient-

specific network address on the network computer system (see column 29, lines 27 - 54 where

the change of patient status creates an alarm requiring different medication).

75.   As per claim 70, Martino teaches the method of 62 as described above.   Martino further

teaches the method comprising

- A first authorised user communicating a prescription authorisation command to a

    pharmacy network computer system (see column 26, lines 42 – 65 where the data

    transaction system transmits a prescription to a pharmacist);

- A second authorised user receiving said prescription authorisation command from the

    pharmacy network computer system (see column 26, lines 42 – 65 where the pharmacist

    receives the transmitted prescription).

Martino does not explicitly teach said second authorised user preparing the prescription for the

patient based on the prescription authorisation, wherein the pharmacy network computer system

is arranged for communication with the network computer system.

However, Freeman teaches said second authorised user preparing the prescription for the patient

based on the prescription authorisation, wherein the pharmacy network computer system is

arranged for communication with the network computer system (see column 8, lines 37 – 43

where the prescription is filled based upon the notification sent through the connected network).

It would be obvious to one of ordinary skill in the art at the time of the invention to add this

feature into Martino. One of ordinary skill in the art would have added this feature into Martin

with the motivation to provide the monitoring and management of a cooperative health care

provision system through a management service (see Freeman column 3, lines 35 – 37).

76.   **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S.

Patent Number 6,044,382 in view of Blaze, U.S. Patent Number 5,721,777.

77.   As per claim 31, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach a system enabling the patient to define permissions or

authorisations at the time of data collection, data transfer, data storage and data access.

However, Blaze teaches a system enabling the patient to define permissions or authorisations at

the time of data collection, data transfer, data storage and data access (see column 7, lines 45 –

56).

It would have been obvious to one or ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to allow emergency access but still permit the patient to control the

routine use of his private records (see column 7, lines 53 – 57).

78.   **Claim 45** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martino, U.S.

Patent Number 6,044,382 in view of Menard, U.S. Patent Number 7,138,902.

79.   As per claim 45, Martino teaches the system of claim 42 as described above.

Martino does not explicitly teach a system wherein the communicator communicates with the

second communications device using spread spectrum radiofrequency signals.

However, Menard teaches a system wherein the communicator communicates with the second

communications device using spread spectrum radiofrequency signals (see column 7, lines 14 –

48).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide health care professionals with access to information for

remote diagnostic capabilities; to provide notification of acute conditions possibly requiring

immediate assistance, transportation to a medical center, or remote treatment action; to provide a

location information of mobile persons for caregivers; to notify responsible parties of the

occurrence of a medical condition; and to provide remote intervention assistance by caregivers

through verbal or visual interaction (see Menard, column 2, lines 14 – 21).

80.   **Claims 51 – 59 and 78** are rejected under 35 U.S.C. 103(a) as being unpatentable over

Martino, U.S. Patent Number 6,044,382 in view of Burton, U.S. Patent Number 6,349,724.

81.   As per claim 51, Martino teaches the system of claim 1 as described above.

Martino does not explicitly teach a system wherein the plural patients have related respiratory

conditions and each patient electronic data collector additionally comprises a sensor which

senses the breath of a user, wherein the sensor communicates breath data to the patient electronic

data collector.

However, Burton teaches a system wherein the plural patients have related respiratory conditions

and each patient electronic data collector additionally comprises a sensor which senses the breath

of a user, wherein the sensor communicates breath data to the patient electronic data collector

(see abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

82.   As per claim 52, Martino in view of Burton teaches the system of claim 51 as described

above.

Martino does not explicitly teach the system wherein said sensor comprises a breath-movable

element which is movable in response to the breath of a patient.

However, Burton teaches the system wherein said sensor comprises a breath-movable element

which is movable in response to the breath of a patient (see column 8, lines 1 – 14).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

83.   As per claim 53, Martino in view of Burton teaches the system of claim 52 as described

above.

Martino does not explicitly teach the system wherein said breath-movable element is selected

from the group consisting of a vane, a sail, a piston and an impeller.

However, Burton teaches the system wherein said breath-movable element is selected from the

group consisting of a vane, a sail, a piston and an impeller (see column 3, lines 52 – 63 where the

exhaled breadth creates the low pressure that then changes the impeller movement).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

84.   As per claim 54, Martino in view of Burton teaches the system of claim 52 as described

above.

Martino does not explicitly teach the system wherein the sensor comprises <u>a pressure sensor for</u>

<u>sensing the pressure profile associated with the breath of a user</u>.

However, Burton teaches the system wherein the sensor comprises a pressure sensor for sensing

the pressure profile associated with the breath of a user (see column 5, lines 49 – 64 where the

valve senses the pressure from inhaling and exhaling).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

85.   As per claim 55, Martino in view of Burton teaches the system of claim 52 as described

above.

Martino does not explicitly teach the system wherein said the sensor comprises <u>an airflow sensor</u>

<u>for sensing the airflow profile associated with the breath of a user.</u>

However, Burton teaches the system wherein said the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user (see column 5, lines 49 – 64 where the valve senses the pressure from inhaling and exhaling).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (see Burton column 2, lines 26 – 27).

86.   As per claim 56, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein the sensor comprises <u>a temperature sensor for sensing the temperature profile associated with the breath of a user.</u>

However, Burton teaches the system wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user (see column 8, lines 27 – 45 where the temperature is taken from the air flow).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Martino. One of ordinary skill in the art would have added this feature into Martino with the motivation to provide accurate pressure control for inspiration and expiration pressure delivered to the patient (see Burton column 2, lines 26 – 27).

87.   As per claim 57, Martino in view of Burton teaches the system of claim 52 as described above.

Martino does not explicitly teach the system wherein the sensor comprises <u>a moisture sensor for sensing the moisture profile associated with the breath of a user</u>.

However, Burton teaches the system wherein the sensor comprises a moisture sensor for sensing

the moisture profile associated with the breath of a user (see column 3, line 64 through column 4,

line 7 where the humidity sensor maintains the moisture in conjunction with the patients breath).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

88.   As per claim 58, Martino in view of Burton teaches the system of claim 52 as described

above.

Martino does not explicitly teach the system wherein the sensor comprises <u>a gas sensor for</u>

<u>sensing the oxygen or carbon dioxide profile associated with the breath of a user</u>.

However, Burton teaches the system wherein the sensor comprises a gas sensor for sensing the

oxygen or carbon dioxide profile associated with the breath of a user (see column 8, lines 27 – 44

where the system has an oxygen sensor).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

89.   As per claim 59, Martino in view of Burton teaches the system of claim 51 as described

above.

Martino does not explicitly teach the system wherein <u>said breath data includes breath cycle data</u>.

However, Burton teaches the system wherein said breath data includes breath cycle data (see

column 8, lines 27 – 44 where the breathing rate, breathing volume, and breathing time).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

90.   As per claim 78, Martino in view of Burton teaches the system of claim 51 as described

above.

Martino does not explicitly teach the system wherein said breath data includes peak flow data.

However, Burton teaches the system wherein said breath data includes peak flow data (see

column 8, lines 27 – 44 where the breathing rate, breathing volume, and breathing time provide

maximum and minimum breathing rates).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add

this feature into Martino. One of ordinary skill in the art would have added this feature into

Martino with the motivation to provide accurate pressure control for inspiration and expiration

pressure delivered to the patient (see Burton column 2, lines 26 – 27).

Conclusion

91.   The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

Boehringer, U.S. Patent Number 4,346,584

Lavin et al., U.S. Patent Number 5,772,585

Ballantyne et al., U.S. Patent Number 5,867,821

Christopher, U.S. Patent Number 5,954,050

Iliff, U.S. Patent Number 6,022,315

Frasca, U.S. Patent Number 6,055,506

Lurie et al, U.S. Patent Number 6,155,257

Joao, U.S. Patent Number 6,283,761

Kummar et al.; U.S. Patent Number 6,416,471

Noble, U.S. Patent Number 6,561,193

Ben-Oren et al., U.S. Patent Number 7,063,667

Simmon et al., U.S. Pre-Grant Publication Number 2002/ 0038378

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neal R. Sereboff whose telephone number is (571) 270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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